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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,412	07/23/2004	Takashi Yasukochi	KUZ-0018	3951

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09/18/2008

EXAMINER
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CHEUNG, WILLIAM K

ART UNIT	PAPER NUMBER
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1796

MAIL DATE	DELIVERY MODE
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09/18/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/502,412	<b>Applicant(s)</b> YASUKOCHI ET AL.	
	<b>Examiner</b> WILLIAM K. CHEUNG	<b>Art Unit</b> 1796	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 August 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 5,7,10-12,16-18,21-23 and 27-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5,7,10-12,16-18,21-23 and 27-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Request for Continued Examination***

1. The request filed on August 28, 2008 for a Request for Continued Examination (RCE) under 37 CFR 1.53(d) based on parent Application No. 10/502,412 is acceptable and a RCE has been established. An action on the RCE follows.
2. In view of the amendment filed August 28, 2008, claims 1-4, 6, 8, 9, 13-15, 19, 20, 24-26 have been cancelled and new claims 30-33 have been added. Claims 5, 7, 10-12, 16-18, 21-23, 27-33.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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4. Claims 5, 7, 10-12, 16-18, 21-23, 27-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamiyama (WO 99/02141) in view of Matsumoto et al. (US 5,532,373), for the reasons adequately set forth from paragraph 8 of the office action of October 24, 2007.

Claim 27 (currently amended): A process for the production of a medical patch, said process comprising:

(a) dissolving in a lower alcohol:

(i) ~~a hormonal drug selected from estradiol and norethisterone acetate~~ one or more drugs; and

(ii) ~~an acrylic polymer copolymer or a methacrylic polymer copolymer comprising one or more crosslinkable acrylic or methacrylic monomer units having at least one hydroxyl group and/or carboxyl group in a crosslinkable monomer unit and one or more other monomer units containing at least 2-ethylhexyl acrylate and/or vinylpyrrolidone;~~

(b) adding to the solution of step (a) one or more crosslinking agents selected from the group consisting of metal alcoholates, boric acid, borate and borate ester;

(c) spreading the mixture of step (b) on a film; and

(d) thermally crosslinking the polymer of (ii) with the one or more crosslinking agents of step (b) either simultaneously with or followed by laminating to a support, collectively thereby to form the medical patch.

Claim 28 (currently amended): A process for the production of a medical patch, said process comprising:

(a) dissolving in a lower alcohol:

(i) ~~a drug selected from estradiol and norethisterone acetate~~ one or more drugs; and

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(ii) one or more crosslinking agents selected from the group consisting of metal alcoholates, boric acid, borate and borate ester;

(b) adding to the solution of step (a) an acrylic ~~polymer copolymer~~ or a methacrylic ~~polymer copolymer~~ having one or more crosslinkable acrylic or methacrylic monomer units having at least one hydroxyl group and/or carboxyl group in a crosslinkable monomer unit and one or more other monomer units containing at least 2-ethylhexyl acrylate and/or vinylpyrrolidone to the solution;

(c) spreading the mixture of step (b) on a film; and

(d) thermally crosslinking the polymer of step (b) with the one or more crosslinking agents of (ii) either simultaneously with or followed by laminating to a support, collectively thereby to form the medical patch.

Kamiyama (abstract) discloses a process for preparing transdermal patches comprising an adhesive. Kamiyama (page 5, line 20-28) discloses that the preparation of the adhesive compositions mixing acrylic based materials and polar monomers such as hydroxyethyl acrylate (typically is referred as 2-hydroxyethylacrylate) and hydroxypropyl acrylate (typically is referred as 3-hydroxypropyl acrylate), and vinyl pyrrolidone to enhance drug solubility of drugs (page 2, line 3; page 6, line 1-6; page 27, claims 11, 16), such as oestradiol and norethisterone (page 13, line 3-4). Kamiyama clearly teach the use of 2-ethylhexyl acrylate (page 5, line 24) and vinyl pyrrolidone (page 6, line 4-5).

Regarding the claimed "spreading the mixture on a film", Kamiyama (page 14, example 1) clearly discloses preparing the adhesive composition comprising the drugs by mixing, and applied to a backing film, and the film is allowed to dry. The disclosed

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drying step also indicates that the prepared adhesive film product is substantially free of water, thereby meeting the "substantially no water" feature of claim 32. Further, the mixing step teachings of Kamiyama also encompass the addition of the ingredients in all possible orders or sequences, which include the adding sequence of claims 27 and 28.

Regarding the new claim 29, Kamiyama (page 2, line 3; page 27, claims 11, 16) clearly teach a process comprising the use of N-vinyl pyrrolidone (or vinyl pyrrolidone).

The difference between the invention of claims 5, 7, 10-12, 16-18, 21-23, 27-33 and Kamiyama is that Kamiyama employs peroxide as curing agent, while the claimed invention involves the use of boric acid.

Matsumoto et al. (col. 1, line 12-33) disclose a process for preparing a photopolymerizable composition for producing lithographic sheets or films, resin reliefs, resists or photomasks or printed circuit board manufacture, black and white or color transfer development sheets or development sheets. Matsumoto et al. (col. 29, 23-38) clearly disclose that the adhesive having a film backing is capable of releasing its content (a dye or a drug). Further, Matsumoto et al. (col. 27, line 65-67) disclose that the composition comprises polyols, a lower alcohol (col. 29, line 21; col. 38, line 10-13), and crosslinking agent such as boric acid (col. 36, line 4). Matsumoto (col. 38, line 11-12) clearly teach using the claimed alcohols such as methanol, ethanol, n-propanol, n-butanol, as coating solvents. Motivated by the expectation of success of developing the coating (adhesive) as described in Matsumoto or Kamiyama, it would have been obvious to one of ordinary skill in art to incorporate the lower alcohols teachings of Matsumoto into the Kamiyama to obtain the lower alcohol feature as claimed. In view of

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such disclosure, it would not be difficult to one of ordinary skill in art that the material compositions of Matsumoto et al. and Kamiyama are very similar, particularly relating to the use of adhesive film for release a substance. Therefore, when Matsumoto et al. (col. 40-43, examples 3-5) disclose a shorter time required for drying at about 100 °C for 2 minutes, and at about 50 °C for 15 minutes when boric acid is used, motivated by the expectation of success of reducing the drying or curing time of Kamiyama, it would also have been obvious to one of ordinary skill in art to replace the peroxide curing system of Kamiyama with the boric acid curing system of Matsumoto et al., or to incorporate the boric acid curing to Kamiyama additionally to the peroxide curing system of Kamiyama to obtain the invention of claims 5, 7, 10-12, 16-18, 21-23, 27-33.

Regarding the claimed "the patch has the pressure-sensitive adhesive power of from 102 gF to 267 gF after storage at 65 °C for 48 hours, in view of the substantially identical type of hydrophilic or polar type monomers (which primarily provide adhesive properties between the adhesive and the substrates) employed in Kamiyama/Matsumoto and as claimed, the examiner has a reasonable basis to believe that the claimed "pressure-sensitive adhesive power" is inherently possessed in the composition as taught in Kamiyama and Matsumoto, in the combined teachings or each individually. Since the PTO does not have proper means to conduct experiments, the burden of proof is now shifted to applicants to show otherwise. In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977); In re Fitzgerald, 205 USPQ 594 (CCPA 1980).

***Response to Arguments***

5. Applicant's arguments in the arguments and in the Declaration filed August 28, 2008 have been fully considered but they are not persuasive.

Applicants argue that Matsumoto et al. teach acrylic resins as the components of their image forming material, which have a high glass transition temperature. Therefore, applicants conclude that the reaction products as described in Matsumoto et al. do not exhibit adhesive property. However, the examiner disagrees because the glass transition temperature of an acrylic material does not provide any information of adhesive properties. Furthermore, applicants must recognize that the resin materials of Matsumoto et al. are required to be adhered to a substrate, even as an imaging material.

Regarding applicants' argument that Matsumoto et al. do not teach the claimed "2-ethylhexyl acrylate and/or vinylpyrrolidone", applicants must recognize that Kamiyama clearly teach the use of 2-ethylhexyl acrylate (page 5, line 24) and vinyl pyrrolidone (page 6, line 4-5) in the disclosed resin composition.

Regarding applicants' disagreement with the examiner rationale that one of ordinary skill in art would be motivated to replace the peroxide of Kamiyama with the boric acid of Matsumoto to obtain the claimed invention because the examples 3 through 5 of Matsumoto do not involve using boric acid, applicants must recognize that the teachings of a prior art is not limited to its preferable embodiment. Applicants must recognize that Matsumoto (col. 36, line 4-10) clearly teach a list of preferable hardeners that include boric acid. In view of their equivalence in importance as a preferable



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hardener, the examiner has a reasonable basis that these hardeners share the same advantage of the shorter drying time as taught in Matsumoto. Applicants must also recognize that one of ordinary skill in art can also employ a mixture of equally important hardener which includes boric acid. Therefore, the examiner has a reasonable basis to believe that the rejection set forth is proper.

Regarding applicants' argument that Matsumoto discloses photobleachable dye layer, intermediate layers and protective layers that are not found in Kamiyama, such argument is not supported by the claims as written. Further, such argument fails to discourage one from combining the teachings of Matsumoto and Kamiyama. Regarding applicants' argument that the Kamiyama and Matsumoto et al. are too far removed from the knowledge of one of ordinary skill in art, and too lacking in the design incentives, to be combined. However, the examiner disagrees because, based on material composition, both Kamiyama and Matsumoto et al. are drawn to substantially identical acrylic based adhesive, film backing and chemical release mechanism for releasing a chemical, drug, or a dye. The mere difference in the intended end use would not deter one of ordinary skill in art from combining the teachings of Kamiyama and Matsumoto et al. Rather, when Matsumoto et al. (col. 40-43, examples 3-5) disclose a shorter time required for drying at about 100 °C for 2 minutes, and at about 50 °C for 15 minutes when boric acid is used, motivated by the expectation of success of reducing the drying or curing time of Kamiyama, it would have been obvious to one of ordinary skill in art to replace the peroxide curing system of Kamiyama with the boric acid curing system of Matsumoto et al. to obtain the invention of claims 5, 7, 10-12, 16-18, 21-23, 27-33.

Regarding applicants argument that Kamiyama describes peroxide as an initiator for polymerization, not as a crosslinking agent, the examiner never dispute with applicants that the peroxides of Kamiyama are crosslinking agent. Nevertheless, the resin system disclosed in Kamiyama can be benefited from the boric acid teachings in Matsumoto. The combined teachings of Kamiyama and Matsumoto do not necessarily mean that the peroxide of Kamiyama is replaced by the boric acid teachings of Matsumoto; the boric acid can be incorporated into Kamiyama without the removal of the peroxides in Kamiyama.

Regarding applicants' argument that the hydroxyl groups should remain in the adhesive layer even after the crosslinking reaction for the solubility of the hydrophilic drug, applicant do not have any evidence to support such argument. Although applicants argue that the boric acid are crosslinked by bonding to the hydroxyl groups, it does not mean all the hydroxyl groups will be consumed by the argued boric acid crosslinking mechanism to cause a change in the solubility of hydrophilic drugs in the disclosed resin composition. Applicants must recognize that crosslinking reactions have very little effect the hydrophilicity of a resin. A hydrophilic polymer after crosslinking is still a hydrophilic crosslinked polymer, such as polyacrylic acid and polyacrylic gel. Both are hydrophilic. Further, applicants must recognize that it does not take much of the hydroxyl groups to be reacted with boric acid to form a gel in view of that the hydrophilic resins are polymeric materials having a high molecular weight. Therefore, applicants' argument is not persuasive.

Regarding applicants' argument on the dye release mechanism, the argument is not supported by the claims as written.

Regarding applicants' argument that the examiner fails to meet the requirement set forth by *KSR International Co. v. Teleflex Inc.*, 550 U.S. , 82 USPQ2d 1385, 1396 (2007), applicants must recognize that although the rationale set forth by the examiner is not same as applicants' rationale, it does not mean that the examiner fails to meet the requirement set forth by *KSR International Co. v. Teleflex Inc.*, 550 U.S. , 82 USPQ2d 1385, 1396 (2007), because the examiner has clearly indicated the reasons for combining the teachings of Kamiyama and Matsumoto.

Regarding claim 27, 31, 32, applicants argue that Kamiyama fails to teach dissolution of a drug and a polymer in a lower alcohol solution before adding a crosslinking agent, applicants must recognize that Matsumoto (col. 38, line 11-12) clearly teach using the claimed alcohols such as methanol, ethanol, n-propanol, n-butanol, as coating solvents. Motivated by the expectation of success of developing the coating (adhesive) as described in Matsumoto or Kamiyama, it would have been obvious to one of ordinary skill in art to incorporate the lower alcohols teachings of Matsumoto into the Kamiyama to obtain the lower alcohol feature as claimed.

Regarding the mixing sequence, applicants must recognize that Kamiyama (page 14, example 1) clearly discloses preparing the adhesive composition comprising the drugs by mixing, and applied to a backing film, and the film is allowed to dry. The disclosed drying step also indicates that the prepared adhesive film product is substantially free of water. Further, the mixing step teachings of Kamiyama also

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encompass the addition of the ingredients in all possible orders or sequences, which include the adding sequence of claims 27. Although peroxide is added in the initial step, applicants argue that Kamiyama does not recite the addition of any crosslinker after the drug and polymer have been dissolved in an alcohol. Applicants must recognize that Matsumoto et al. (col. 27, line 65-67) disclose that the composition comprises polyols, a lower alcohol (col. 29, line 21; col. 38, line 10-13), and crosslinking agent such as boric acid (col. 36, line 4). In view of such disclosure, it would not be difficult to one of ordinary skill in art that the material compositions of Matsumoto et al. and Kamiyama are very similar, particularly relating to the use of adhesive film for release a substance. Therefore, when Matsumoto et al. (col. 40-43, examples 3-5) disclose a shorter time required for drying at about 100 °C for 2 minutes, and at about 50 °C for 15 minutes when boric acid is used, motivated by the expectation of success of reducing the drying or curing time of Kamiyama, it would have been obvious to one of ordinary skill in art to replace the peroxide curing system of Kamiyama with the boric acid curing system of Matsumoto et al. to obtain the invention of claims 5, 7, 10-12, 16-18, 21-23, 27-33. Applicants must also recognize that Kamiyama (page 15, line 3-4) clearly teach that methanol (a lower alcohol) can be used to dissolve drugs. In view of the substantially identical acrylic type polymer disclosed in Kamiyama and as claimed, there is no reason for the examiner that the polymers of Kamiyama can not be dissolved in the lower alcohol of Kamiyama. Regarding applicants' argument that Kamiyama involves using toluene ... and ethyl acetate in page 21 of Kamiyama, applicants must recognize that

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the claims as written “comprising” do not exclude the use of mixed solvent system comprising toluene ... and ethylacetate.

Regarding applicants’ argument that the broad interpretation of “dissolving” does not include mixing or adding, the examiner disagrees because one of ordinary skill in art would have recognized that without bringing a solute and solvent together by mixing or by adding, it would be difficult to dissolve a solute into a solvent.

Regarding applicants’ argument that Matsumoto fails to dissolve a drug and a polymer in lower alcohol, applicants must recognize that such teachings have already been taught by Kamiyama. Regarding applicants’ argument that Matsumoto never add boric acid to a polymer/drug solution, applicants must recognize that when Matsumoto et al. (col. 40-43, examples 3-5) disclose a shorter time required for drying at about 100 °C for 2 minutes, and at about 50 °C for 15 minutes when boric acid is used, motivated by the expectation of success of reducing the drying or curing time of Kamiyama, it would have been obvious to one of ordinary skill in art to replace the peroxide curing system of Kamiyama with the boric acid curing system of Matsumoto et al. to obtain the invention of claims 5, 7, 10-12, 16-18, 21-23, 27-33. Therefore, the examiner has a reasonable basis that the combined teachings of the Kamiyama and Matsumoto et al. would result in dissolving a drug and a polymer in solvent system comprising a lower alcohol. Although the process of Matsumoto et al. involves micro-encapsulation, the micro-encapsulation process is not adequate to prevent the boric acid teaching of Matsumoto to be incorporated into Kamiyama.

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Regarding applicants' argument that the microcapsules typical to Matsumoto are very specific sizes and preferably respond to changes due to pressure under  $10\text{kg/cm}^2$ , applicants must recognize that the argument is not supported by the claims as written. Applicants must recognize that the recited "medical patches" means a film/adhesive comprising a drug. Therefore, since both the films of Kamiyama and Matsumoto are structurally capable of functioning as a medical patch, the rejection set forth is proper. Applicants must recognize that even a medical patch can have other intended uses. And for the same reasons, the film patches as taught in Matsumoto can also be used as medical patches.

Regarding applicants' argument that Matsumoto also teaches other photosensitive components that are related to medical patch application, applicants must recognize that such argument would not prevent the boric acid from being incorporated into Kamiyama because nothing in the claims indicate that the invention as claimed can not be photosensitive.

Regarding applicants' argument that the working examples in Matsumoto do not involve using boric acid, applicants must recognize that the teachings of a prior art is not limited to its working example or preferable embodiments.

In view of the reasons set forth above, the rejection set forth is proper.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William K. Cheung whose telephone number is (571)

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272-1097. The examiner can normally be reached on Monday-Friday 9:00AM to 2:00PM; 4:00PM to 8:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David WU can be reached on (571) 272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/William K Cheung/  
Primary Examiner, Art Unit 1796

William K. Cheung, Ph. D.  
Primary Examiner  
September 15, 2008